DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 1 0 2017

Ms. Karen St. Onge
Director, Quality Assurance/Regulatory Affairs
NxStage Medical, Incorporated
439 South Union Street, 5th Floor
Lawrence, Massachusetts 01843

Re: K012832
Trade/Device Name: ComfortMate Fluid™ Warming System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: August 22, 2001
Received: August 23, 2001

Dear Ms. St. Onge:

This letter corrects our substantially equivalent letter of October 24, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809]), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K012832

439 South Union Street, Suite 501
Lawrence, MA 01843
v: 978.687.4700
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Indications for Use Statement

Device Name:

ComfortMate™ Warming System

Indications for Use:

The ComfortMate™ Fluid Warming System is intended to be used for the warming of fluids prior to administration.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012832

OCT 2 4 2001

NxStage Medical, Inc.
ComfortMate™ Fluid Warming System
510(k) Premarket Notification

K012832

Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	439 South Union Street, 5th Floor Lawrence, MA 01843
Phone:	1-978-687-4700
Fax:	(978) 687-4800
Contact Person:	Karen St. Onge, Director, Quality Assurance/Regulatory Affairs
Date of Preparation:	22 August 2001

B. Device Name:

Trade Name:	ComfortMate™ Fluid Warming System
Common/Usual Name:	Warmer, Thermal, Infusion Fluid
Classification Name:	Warmer, Thermal, Infusion Fluid

C. Predicate Device Name:

The predicate devices for the ComfortMate™ Fluid Warming System are the following:

Warmer:

- Bair Hugger® Blood/Fluid Warmer - #K973741 (4/30/98);
- MaxOne™ IV Fluid/Blood Warmer - #K002409 (6/28/01);
- Medi-Temp II FW300 Blood/Fluid Warmer – Originally 510(k)-cleared as the Dupaco CounterFlo 300 Blood/Fluid Warmer System - #K950038.

Warmer Disposable:

- Bair Hugger® Blood/Fluid Warmer - #K973741 (4/30/98);
  Medi-Temp II FW300 Blood/Fluid Warmer – Originally 510(k)-cleared as the Dupaco CounterFlo 300 Blood/Fluid Warmer System - #K950038.

Summary of Safety and Effectiveness

D. Device Description/Indications for Use:

The ComfortMate™ Fluid Warming System is designed to warm fluids to 30°C to 37°C prior to patient administration, at flow rates of up to 200 ml/min. The ComfortMate™ consists of a reusable fluid warming unit and a single-use warmer disposable. To use the ComfortMate™, the warmer disposable is inserted into the warming unit. Once the warming unit's door is closed, the warmer disposable comes into contact with the warming unit heater plates. Fluids are warmed as they flow through the disposable. The knob on the front panel allows the user to choose from 9 temperature comfort settings. The ComfortMate™ has not been validated for the warming of blood or blood products.

Intended Use

The ComfortMate™ Fluid Warming System is intended to be used for the warming of fluids prior to administration.

E. Substantial Equivalence:

510(k) Substantial Equivalence Decision Making Process

1. **Is the product a device?**

   YES - The components of the ComfortMate™ Fluid Warming System are devices pursuant to 21 CFR §201 [321] (h).

2. **Does the new device have the same intended use?**

   YES – The intended use for the ComfortMate™ Fluid Warming System is equivalent to those for the predicate warming systems.

   ComfortMate™ Fluid Warming System
   The ComfortMate™ Fluid Warming System is intended to be used for the warming of fluids prior to administration.

   Bair Hugger® Ranger Blood/Fluid Warmer (#K973741)
   The Bair Hugger® Blood/Fluid Warmer is intended to warm blood, blood products and liquids.

   MaxOne™ IV Fluid/Blood Warmer (#K002409)
   The MaxOne™ IV Fluid/Blood Warmer is indicated for the warming of blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments.

Medi-Temp II Blood/Fluid Warmer (#K950038)
This device is intended to aid in the prevention of hypothermia during administration of blood, blood products, and other fluids.

3. **Does the device have technological characteristics that raise new types of safety or effectiveness questions?**

   NO – The functional characteristics of the ComfortMate™ Fluid Warming System are equivalent to those of commercially available warming systems and raise no new types of safety or effectiveness questions. In addition, the results of design verification testing indicate that the ComfortMate™ Warming Unit and Disposable function as intended.

4. **Does descriptive or performance information demonstrate equivalence?**

   YES – NxStage Medical, Inc. believes that the information provided in this submission clearly describes the ComfortMate™ Fluid Warming System and demonstrates that it is substantially equivalent to other commercially available warmers.

F. Safety Summary

The ComfortMate™ verification testing rigorously tested the features of the ComfortMate™ system. The results of this testing indicate that the ComfortMate™ system is safe and effective for its intended use.

G. General Safety and Effectiveness Concerns

The device labeling contains an Operator's Manual, which includes indications for use, cautions and warnings, as well as the general operating instructions required for proper use of the ComfortMate™ Fluid Warming System. This information promotes safe and effective use of the device.

Karen St. Onge
Director, Quality Assurance/Regulatory Affairs

8/22/01
Date